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Case No. 131.02US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Inventor(s): Singh et al.

Serial No: 10/812,619

Filed: 30 March 2004

For: Surface Receptor Complexes as  
Biomarkers

Examiner: Not Yet Assigned

Art Unit: 1641

Confirmation No.: 3231

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on the accompanying PTO-1449 form(s) were cited in an International Search Report for the co-pending international patent application PCT/US2004/09717 filed 07 Jan. 2005. A copy of the International Search Report is enclosed. The references cited may be material to the examination of the above-identified application and are, therefore, submitted in compliance with the duty of disclosure defined in 37 CFR 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application. Copies of the cited references are enclosed or have been previously submitted in prior application(s) to the above application.

This Information Disclosure Statement under 37 CFR 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

**SUBMISSION INFORMATION**

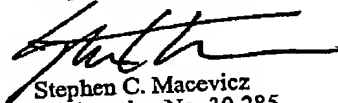
- ☒ This Information Disclosure Statement is being submitted within three (3) months of filing or before mailing of a first Office Action, whichever occurs last. (37 CFR 1.97(b))
- ☐ This Information Disclosure Statement is being submitted before the mailing date of either a final Office Action or a Notice of Allowance. (37 CFR 1.97(c)) Applicant elects to pay the fee set forth in 37 CFR 1.17(p) for submission of the Information Disclosure Statement under 37 CFR 1.97(c).
- ☐ This Information Disclosure Statement is being submitted after the mailing date of a final Office Action or Notice of Allowance, whichever occurs first, but before, or simultaneously with, the payment of the issue fee. (37 CFR 1.97(d)) Applicant hereby petitions for the consideration of this Information Disclosure Statement under 37 CFR 1.97(d)(ii). The petition fee under 37 CFR 1.17(i)(1) is authorized or enclosed as indicated below

**PAYMENT OF FEES (IF ANY DUE)**

**FEE AUTHORIZATION.** The Commissioner is hereby authorized to withdraw from Deposit Account **50-2266**

any submission fees or petition fees required for this Information Disclosure Statement.

Respectfully submitted,

  
Stephen C. Macevitz  
Registration No. 30,285

Enclosures: 1449 form(s)  
Copy of International Search Report

Form PTO-1449 (adapted)  <b>REFERENCES CITED BY APPLICANT</b>  Page 1 of 1	Docket No. <b>Aclara ref. 131.02US</b>	Serial No. <b>10/812,619</b>
	Applicant <b>Chan-Hui et al</b>	
	Filing Date <b>30 March 2004</b>	Group <b>1641</b>

## U.S. PATENT DOCUMENTS

Examine r's Initial		Document Number	First Inventor	Class /Subclass	Title	Issue/Publ. Date (mm/dd/yyyy)
	P1	US2002/0127654A1	Price et al	435/69.5	Compositions and Methods for Production Cell Culture	12 Sept. 2002
	P2	US2002/0164641A1	McTigue et al	435.7.1	Modifications of VEGF Receptor-2 Protein and Methods of Use	07 Nov. 2002

EXAMINER	Date considered
*EXAMINER: Initial if reference considered, whether or not citation in conformance with MPEP 609; Draw line through citation if not in conformance and/or not considered. Include copy of this form with next communication to applicant.	

BEST AVAILABLE COPY

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 131.02WO	<b>FOR FURTHER ACTION</b>	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US04/09717	International filing date (day/month/year) 30 March 2004 (30.03.2004)	(Earliest) Priority Date (day/month/year) 01 April 2003 (01.04.2003)
Applicant ACLARA BIOSCIENCES, INC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the Report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures

Form PCT/ISA/210 (first sheet) (July 1998)

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US04/09717

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G01N 33/543  
US CL : 435/7.1  
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
U.S. : 435/7.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0127654 A1 (PRICE et al) 12 September 2002 (12.09.2002), paragraph 0031.	1-2
Y	US 2002/0164641 A1 (MCTIGUE et al) 07 November 2002 (07.11.2002), abstract,	5-11, 13, 15-18
A	summary, see entire document.	8, 12, 14, 19-25

☐ Further documents are listed in the continuation of Box C.

See patent family annex.

Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;"

document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

03 January 2005 (03.01.2005)

07 JAN 2005

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (703) 305-3230

Authorized officer

Deborah A Davis

Telephone No. (572) 272-0818

Jean P. P. P.  
Paralegal

Form PCT/ISA/210 (second sheet) (July 1998)

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITYTo:  
STEPHEN C. MACEVICZ  
ACLARA BIOSCIENCES, INC.  
1288 PEAR AVENUE  
MOUNTAIN VIEW, CA 94043

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year)

07 JAN 2005

FOR FURTHER ACTION

See paragraph 2 below

Applicant's or agent's file reference

131.02WO

International application No.

International filing date (day/month/year)

30 March 2004 (30.03.2004)

Priority date (day/month/year)

01 April 2003 (01.04.2003)

PCT/US04/09717

International Patent Classification (IPC) or both national classification and IPC

IPC(7): G01N 33/53 and US Cl.: 435/7.1

Applicant

ACLARA BIOSCIENCES, INC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230  
Form PCT/ISA/237 (cover sheet) (January 2004)

Authorized officer

Deborah A Davis

Telephone No. (572) 272-0818

Jean Proctor  
Paralegal Specialist

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/09717

## Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Form PCT/ISA/237(Box No. 1) (January 2004)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITYInternational application No.  
PCT/US04/09717

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)

Claims 3-25

YES

Claims 1-2

NO

Inventive step (IS)

Claims 3-4, 8, 12, 14, 19-25

YES

Claims 1-2, 5-7, 9-11, 13, 15-18

NO

Industrial applicability (IA)

Claims 1-25

YES

Claims NONE

NO

## 2. Citations and explanations:

Claims 1-2 lack novelty under PCT Article 33(2) as being anticipated by Price et al US 2002/0127654. Price et al teaches methods of detecting cell surface receptors that express proteins related to breast, colon and prostate cancer (paragraph 0031.)

Claims 5-7, 9-11, 13, 15-18 lacks an inventive step under PCT Article 33(3) as being obvious over Price et al in view of McTigue et al US 2002/0164641.

McTigue et al teaches receptors such as VEGFR, PDGFR and others that serve as potential makers in the screening process for tumor suppressor drugs paragraph 0019, 0020 and 0022. It would have been obvious to modify the teachings of Prices et al to include detection of these receptor markers because they are instrumental in screening for new drugs.

Claims 1-25 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Form PCT/ISA/237 (Box No. V) (January 2004)



## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

**"Statement under Article 19(1)" (Rule 46.4)**

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

**Consequence if a demand for international preliminary examination has already been filed**

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

**Consequence with regard to translation of the international application for entry into the national phase**

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.